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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,455	04/19/2002	Tahmina Mujtaba	UT-0033	1827
26259 75	90 05/04/2005		EXAM	INER
LICATLA & TYRRELL P.C.			WARE, DEBORAH K	
66 E. MAIN STREET MARLTON, NJ 08053			ART UNIT	PAPER NUMBER
•			1651	•

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	10/009,455	MUJTABA ET AL.				
Office Action Summary	Examiner	Art Unit				
•	Deborah K. Ware	1651				
The MAILING DATE of this communication						
Period for Reply						
A SHORTENED STATUTORY PERIOD FOR RETHE MAILING DATE OF THIS COMMUNICATIO  - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a  - If NO period for reply is specified above, the maximum statutory per  - Failure to reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the material patent term adjustment. See 37 CFR 1.704(b).	N. 1.136(a). In no event, however, may reply within the statutory minimum of t iod will apply and will expire SIX (6) Mutute, cause the application to become	a reply be timely filed  nirty (30) days will be considered timely.  DNTHS from the mailing date of this communication.  ABANDONED (35 U.S.C. § 133).				
Status						
1)⊠ Responsive to communication(s) filed on 14 January 2005.						
· _ · <del></del>						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) ☐ Claim(s) 1-8 is/are pending in the application. 4a) Of the above claim(s) 1-3,7 and 8 is/are withdrawn from consideration.  5) ☐ Claim(s) is/are allowed.  6) ☐ Claim(s) 4-6 is/are rejected.  7) ☐ Claim(s) is/are objected to.  8) ☐ Claim(s) are subject to restriction and/or election requirement.						
Application Papers	inor					
9) The specification is objected to by the Exam 10) The drawing(s) filed on is/are: a) □ a		o by the Examiner				
Applicant may not request that any objection to t						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11)☐ The oath or declaration is objected to by the	Examiner. Note the attach	ed Office Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some col None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449 or PTO/SB/Paper No(s)/Mail Date <u>5/6/03</u>.</li> </ol>	Paper N 08) 5) Notice o	o Summary (PTO-413) p(s)/Mail Date f Informal Patent Application (PTO-152) Note: Not all inventors sugned declaration				

#### **DETAILED ACTION**

Claims 1-8 are presented for examination on the merits.

#### Amendment and Declaration

The amendment and declaration of September 29, 2004, are acknowledged.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### Election/Restrictions

Applicant's election with traverse of Group II, claims 4-6, in the reply filed on January 14, 2005 is acknowledged. The traversal is on the ground(s) that no lack of unity was required in the PCT case and that a serious burden or showing of independent and distinct claims have been set forth in the restriction. This is not found persuasive because firstly the PCT case was directed to a differently claimed invention than newly presented by Applicants' last filed paper amendment of September 29, 2004, wherein a much higher purity is deemed the critical technical feature of the instantly claimed invention. Secondly, a serious burden of search is presented to the examiner to search for such a high purity of product using such different techniques and methods for obtaining the newly claimed highly pure product of glial-restricted precursor cells. Thirdly, therefore, the claimed inventions as set forth in the restriction requirement are independent and distinct from each other for these reasons as well as those of record. Also, applicants should note that at page 1, line 1 of the instantly filed specification there is no reference to the PCT/US00/12446 filed May 5, 2000 for which

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this application is a 371 thereof. Applicant is directed to insert the same at page 1, line 1, of the specification, including of which that PCT claims benefit of 60/133,159 filed March 7, 1999.

Claims 1-3 and 7-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on January 14, 2005.

The requirement is still deemed proper and is therefore made FINAL.

#### Information Disclosure Statement

The information disclosure statement (IDS) submitted on May 6, 2003, was received. Accordingly, the information disclosure statement is being considered by the Examiner. The examiner was not aware that this paper had been filed in IFW at the time the first office action was done, and so it is being submitted now for consideration but given the date it was filed.

# Claim Rejections - 35 USC § 102

The amendments presented September 29, 2004, have removed the prior rejections under this statute because the reference do not teach the greater than 95% purity.

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## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

\_ \_ \_ \_Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rao et al (March 1998, BF citation on enclosed PTO-1449 Form).

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Claims are newly drawn to greater than 95% pure population of mouse glial-restricted precursor cells derived from mouse neural tubes at embryonic day 12.0 or mouse or mouse embryonic stem cells by A2B5+ immunoreactivity. Furthermore, methods for isolating them are also claimed.

Rao et al teach isolated glial restricted precursor cells from spinal cords of rats using procedures in vitro A2B5+ immunoreactivity. See the abstract. Also, after the abstract, at col. 1, of page 3996, lines 13-14, the best defined glial prescursor cell is the A2B5+ progenitor cells (stem cells) isolated from rat embryos. Spinal chord tissue is used which comprises the neural tube.

The claims differ from Rao et al in that rats are used and not a mouse to obtain the cells in greater than 95% purity.

It would have been obvious to one of ordinary skill in the art to isolate the cells from a mouse because Rao et al disclose the use of rats for isolating the cells. To obtain them in an amount of greater purity of 95% while using the methods of obtaining these cells as disclosed by Rao et al. would have been expected to provide successful results. Method for isolating these cells by A2B5+ immunoreactivty is disclosed by Rao et al. Therefore, to incubate and isolate them would have been expected to yield greater than 95% purity because the central nervous system of a rodent is known to have greater than 90% glial cells. The claims are rendered prima facie obvious over the newly applied art reference.

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rao et al.

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Claims are newly drawn to greater than 95% pure population of mouse glial-restricted precursor cells derived from mouse neural tubes at embryonic day 12.0 or mouse or mouse embryonic stem cells by A2B5+ immunoreactivity. Furthermore, methods for isolating them are also claimed.

Rao et al teach isolated rat neuron-restricted precursor cells derived from neural tubes and methods therefore. Note the abstract and col. 5, lines 40-45 and 63 and col. 6, lines 5-15 and col. 9, example 1. Note also col. 13, lines 55-63, col. 4, lines 40-66, and col. 5, lines 1-25. Further, see col. 9, lines 20-22.

Claims differ from Rao et al in that greater than 95% purity is not claimed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was claimed to increase the number of glial restricted cells obtained by the methods of Rao et al in order to enhance the purity of the population because these cells are present in the central nervous system at a level of 90%. One of skill in the art would have expected successful results for isolating these cells at a greater purity of 95% while using the methods of obtaining these cells as disclosed by Rao et al. Rao et al teach that the neural tube undergoes closure at day 10, note col. 9, lines 20-22 and further teach that developing cultures were terminated at day 12, note col. 13, line 62. Thus, one of skill would have expected successful results for obtaining these cells in pure populations at day 12 because Rao et al does teach that they come from the same source, the neural tube. Using the same procedures as Rao et al and the same class source, rodent, would have been expected to provide a successful yield of pure cells.

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Each of the process steps employed by Applicants' claimed methods of isolating the cells are disclosed by Rao et al. Note col. 4-5, lines 40-66 and lines 1-26. Steps of removing a neural tube, dissociation of cells from the tube, plating the cells, culturing the cells and isolating the cells are disclosed. In the absence of persuasive evidence to the contrary the claims are rendered prima facie obvious over the cited prior art.

### Response to Arguments

Regarding Applicants' arguments that Rao et al is not valid reference because of they have declared in the declaration that it is the word of Rao et al that it is his work alone, it should be noted that the M.P.E.P. 1.131 (b) states that: The showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application. Original exhibits of drawings or records, or photocopies thereof, must accompany and form part of the affidavit or declaration or their absence satisfactorily explained. Applicants have not provided sufficient showing in their declaration in accordance with the M.P.E.P. However, the amendments of September 29, 2004, were sufficient in removing the reference as a 102 against the claims, but the reference is deemed to make the claimed subject matter obvious over the cited prior art for reasons discussed above. Also not all inventors signed the declaration.

#### Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

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F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 4 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 15 of U.S. Patent No. 6,361,996.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claim reads on isolated pure glial-restricted precursor cells from a neural tube, note lines 19-21, of col. 24 (see claim 15).

Claim 15 teaches isolated, pure population of glial-restricted cells from a rat embryo and specifically its neural tube.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was claimed to increase the number of glial restricted cells obtained by the methods of Rao et al in order to enhance the purity of the population because these cells are present in the central nervous system at a level of 90%. One of skill in the art would have expected successful results for isolating these cells at a greater purity of 95% while using the methods of obtaining these cells from a neural tube as claimed by Rao et al.

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All claims fail to be patentably distinguishable over the state of the art discussed

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above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are

properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are

cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Deborah K. Ware whose telephone number is 571-272-

0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

Deborah K. Ware April 30, 2005

DAVID M. NAFF PRIMARY EXAMINER

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